DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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June 10, 2015

Osteomed Implantes, LTDA
% Mr. J.D. Webb
The OrthoMedix Group, Incorporated
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K143572
Trade/Device Name: Intersomatic Cervical Device - DICOM PEEK, Intersomatic Intervertebral Space Maintenance Device - DIMEI PEEK, Intersomatic Transforaminal - TLIF PEEK
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP, MAX
Dated: May 3, 2015
Received: June 5, 2015

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143572

Device Name
Intersomatic Cervical Device - DICOM PEEK, Intersomatic Intervertebral Space Maintenance Device - DIMEI PEEK, Intersomatic Transforaminal - TLIF PEEK

Indications for Use *(Describe)*

The Intersomatic Cervical Device - DICOM PEEK is intended for anterior interbody spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one disc level (C2-C3 disc to the C7-Tl disc). Cervical degenerative disc disease is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. This device is intended for use with additional supplemental fixation systems and autogenous bone graft implanted via an open, anterior approach. Patients should have at least six weeks of non-operative treatment prior to treatment with intervertebral cage.

The Intersomatic Intervertebral Space Maintenance Device - DIMEI PEEK and Intersomatic Transforaminal - TLIF PEEK is indicated for intervertebral body spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). DIMEI and TLIF Spinal Implants are to be used with autogenous bone graft and implanted via an open posterior or transforaminal approach. The DIMEI and TLIF Spinal Implant is to be used with additional supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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*5*10(k) Summary: DICOM PEEK and DIMEI PEEK

Date Prepared	April 20, 2015
Submitted By	Osteomed Implantes, LTDA Washington Luiz Road, km 172 Condomínio Conpark – Rua 6, S/N CEP 13501-600 Rio Claro - SP BRAZIL (19) 3532-3411 Tele
Contact	J.D. Webb 1001 Oakwood Blvd Round Rock, TX 78681 512-388-0199 Tele 512-692-3699 Fax e-mail: jdwebb@orthomedix.net
Trade Name	Intersomatic Cervical Device - DICOM PEEK Intersomatic Intervertebral Space Maintenance Device – DIMEI PEEK Intersomatic Transforaminal – TLIF PEEK
Common Name	intervertebral body fusion device
Classification Name	intervertebral body fusion device - cervical intervertebral body fusion device - lumbar
Class	II
Product Code	ODP MAX
CFR Section	21 CFR section 888.3080
Device Panel	Orthopedic
Primary Predicate Device	Stryker Spine AVS® TL PEEK Spacer (K083661)
Secondary Predicate Devices	Zimmer, BAK/C Vista Interbody Fusion (P980048 S3) Spinal Elements, Crystal Cervical/Lucent Straight Interbody Cages K071724/K073351/K081968) LDR Spine Cervical Interbody Fusion System (K091088) SeaSpine, Pacifica Cage (K082310) DePuy, Brantigan I/F Cage (P960025) Surgical Dynamic, Ray Threaded Lumbar Fusion Cage (P950019) Meditech Advisors, Talos PLIF (K090707)

Device Description	The Intersomatic Cervical Device - DICOM PEEK, Intersomatic Intervertebral Space Maintenance Device – DIMEI PEEK and Intersomatic Transforaminal – TLIF PEEK were developed as implants for the stabilization of the cervical and lumbar spinal column. The implants have ridges on both their inferior and superior surfaces to prevent migration, and graft windows which help facilitate bony integration. X-ray markers are integrated for visualization of the implants during and after surgery.
Materials	Invibio® PEEK Optima LT1 (ASTM F2026) Titanium alloy conforming to ASTM F136
Substantial Equivalence Claimed to Predicate Devices	The Intersomatic Cervical Device - DICOM PEEK, Intersomatic Intervertebral Space Maintenance Device – DIMEI PEEK and Intersomatic Transforaminal – TLIF PEEK are substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.
Indications for Use	The Intersomatic Cervical Device - DICOM PEEK is intended for anterior interbody spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one disc level (C2-C3 disc to the C7-T1 disc). Cervical degenerative disc disease is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. This device is intended for use with additional supplemental fixation systems and autogenous bone graft implanted via an open, anterior approach. Patients should have at least six weeks of non-operative treatment prior to treatment with intervertebral cage. The Intersomatic Intervertebral Space Maintenance Device – DIMEI PEEK and Intersomatic Transforaminal – TLIF PEEK is indicated for intervertebral body spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). DIMEI and TLIF Spinal Implants are to be used with autogenous bone graft and implanted via an open posterior or transforaminal approach. The DIMEI and TLIF Spinal Implant is to be used with additional supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.
Non-clinical Test Summary	The following analyses were conducted: • Static and dynamic compression per ASTM F2077 • Static and dynamic torsion per ASTM F2077 • Subsidence per ASTM F2267 The results of these evaluations indicate that the DICOM PEEK, DIMEI PEEK and TLIF PEEK are equivalent to predicate devices.
Clinical Test Summary	No clinical studies were performed
Conclusions: Non-clinical and Clinical	Osteomed Implantes considers the DICOM PEEK, DIMEI PEEK and TLIF PEEK to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use